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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/042,203 | 01/11/2002 | Bernd Riedl | BAYER 25A | 6634 |

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EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/042,203 | RIEDL ET AL. |
| | Examiner RITA J. DESAI | Art Unit 1625 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 50-54 and 68-109 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 50-54 and 68-109 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The request filed on 10/30/02 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10042203 is acceptable and a RCE has been established. An action on the RCE follows.

Information Disclosure Statement

The information disclosure statement filed 10/30 and 11/19/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Also the 1449 has application numbers without publication dates and would not be printed but just kept in the file.

Applicants should send in a copy of the pending claims.

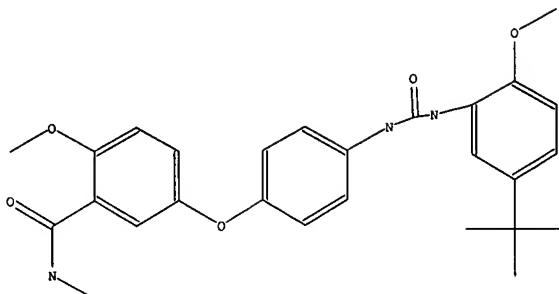
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-54, 68-73, 105-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al 5447957.

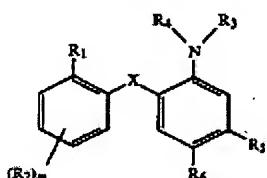
The instant invention is drawn to pharmaceutical salts and method of treating wherein the compounds have the formula



Scope and Content of Prior Art MPEP 2141.01

The reference teaches compounds and pharmaceutical salts of formula

1. A compound of the formula:



wherein

R1 is $(CH_2)_nOH$ or $(CH_2)_nCO_2R_5$;

n is 0 or an integer having a value of 1;

X is oxygen or sulfur;

R2 is hydrogen, halogen, optionally substituted C_{1-4} alkyl, or C_{1-4} alkoxy;

m is an integer having a value of 1 or 2;

R3 is $C(O)R_1$;

R4 is hydrogen, or C_{1-4} alkyl;

R5 is hydrogen, halogen, CF_3 , CH_3 , $(CH_2)_2C(O)_2R_9$, or $(CH_2)_2OH$;

t is 0 or an integer having a value of 1 or 2;

R6 is hydrogen or halogen;

R7 is NR_9R_{10} ;

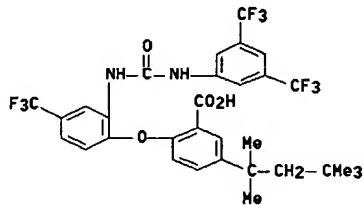
R8 is hydrogen or C_{1-4} alkyl;

R9 is hydrogen or C_{1-4} alkyl;

R10 is hydrogen, optionally substituted aryl, optionally substituted aryl C_{1-3} alkyl, optionally substituted C_{1-3} alkyl, or together R9 and R10 with the nitrogen to which they are attached form a 5 to 7

This is a genus which would encompass the species of the instant invention.

See the species given below.



Difference Between the Prior Art and the Claims MPEP 2141.02

The reference teaches a small genus with the trifluoro substitutents not the specific compounds.

Prima Facie Obviousness Rational and Motivation MPEP 2142-2143

One of skill in the art would have found it obvious and have been motivated to modify the compounds to obtain new compounds since the reference has a small genus of compounds with pharmaceutical activities.

Double Patenting

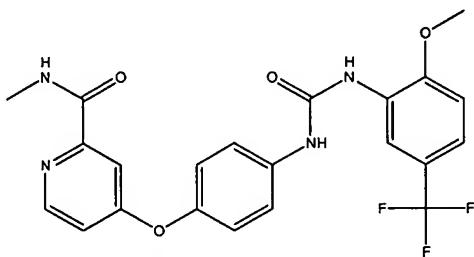
A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 68-109 and 50-54 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 17,18,22-25 of copending Application No. 10071248. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim 74 of US 10042203 discloses the following compound.



N-(2-methoxy-5-(trifluoromethyl)phenyl)-N'-(4-(2-(N-methylcarbamoyl)-4-pyridyloxy)phenyl)urea

Applicants are also required to review the claims of their various co-pending applications for Double Patenting.

Since examiner has not been able to obtain the various applications , it would be helpful if applicants could provide the pending claims.

Claims 68-109 and 50-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 68 of copending Application No. 09/773604, 09/773659, 09/773658, 09/773672, 09773675 ,09/755060, 08/863022, 09/947,761, 09/776,936 . Although the conflicting claims are not identical, they are

not patentably distinct from each other because the claims read on the claims of the instant application. The genus of the claims encompasses the species found in this application. The prior applicants have claims drawn to compounds, pharmaceutical salts and methods of treating.

The instant application is drawn to the pharmaceutical salts of these compounds and methods of treating.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The various applications cited on the 1449 have the claims still drawn to the ureas or diphenyl ureas, and since applicants have not amended the claims to the elected group in some of the applications, these claims read on the applicants claimed species.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



R.D.
January 21, 2003